REMARKS

Reconsideration of this application is respectfully requested. Claims 1-54 have been canceled. Claims 55-66 are new and are derived from the canceled claims. New claims 55-66 read on the elected invention. The amendment adds no new matter.

Withdrawal of the Finality of the Office Action

Applicant submits that the finality of the November 18, 2009, Office Action was **PREMATURE** and respectfully requests withdrawal of the finality of the Office Action. The Examiner raised two new rejections, under 35 U.S.C. § 101 and 35 U.S.C. § 102, which were not necessitated by Applicant's prior amendment. In Applicant's last response, claim 36 was amended to incorporate the limitations of claim 34, as suggested by the Examiner. Thus, there is no reason why the issues under 35 U.S.C. § 101 and 35 U.S.C. § 102 could not have been previously raised by the Examiner. Accordingly, Applicant submits that the finality of the November 18, 2009, Office Action is improper and should be withdrawn. See M.P.E.P. § 706.07(a).

Rejections under 35 U.S.C. § 101

Claims 36, 37, and 54 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The Examiner contends that the claims encompass naturally-occurring compounds. Applicant traverses the rejection.

New claims 55-66 recite that the polypeptide comprises or consists of the amino acid sequence set forth in SEQ ID NO:2, residues 17-677, as recited in

canceled claims 36, 37, and 54. The amino acid sequence set forth in SEQ ID NO:2, residues 17-677 is not found in nature. Rather, SEQ ID NO:2 contains amino acid residues from tetanus toxoid within the HER -2 amino acid sequence. (Specification at 12, lines 9-13.) The HER-2 protein found in nature would not have amino acid residues from tetanus toxoid within it; rather, such a polypeptide must be made by man. Therefore, Applicant's claims 55-66 are not found in nature. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 36-44, 46, and 55 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because of the recitation of "immunogenic variant" in claims 36 and 54. Applicant traverses the rejection.

Applicant notes that there was previously no claim 55 in this case.

Clarification is respectfully requested.

Applicant submits that the term "immunogenic variant" is understood by the skilled artisan, and that the inclusion of this term does not make Applicant's claims indefinite.

Nonetheless, new claims 55-66 do not recite the term "immunogenic variant." In this way, claims 55-66 are not limited to immunogenic variants of HER-2. Accordingly, Applicant submits that this rejection has been obviated.

Rejections under 35 U.S.C. § 102

Claims 36-44, 46, and 55 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 00/20027. The Examiner contends that HER-2 (SEQ ID NO:3) of WO 00/20027 meets the limitations of claim 36-44, 46, and 55. Applicant traverses the rejection.

Applicant notes that there was previously no claim 55 in this case.

Clarification is respectfully requested.

New claims 55-66 recite that the polypeptide comprises or consists of the amino acid sequence set forth in SEQ ID NO:2, residues 17-677, as recited in canceled claims 36-44, 46, and 54. The amino acid sequence set forth in SEQ ID NO:2, residues 17-677 is not the same as the amino acid sequence of SEQ ID NO:3 of WO 00/20027. Rather, SEQ ID NO:2 contains amino acid residues from tetanus toxoid within the HER-2 amino acid sequence. (Specification at 12, lines 9-13.) SEQ ID NO:3 of WO 00/20027 does not contain these amino acid residues from tetanus toxoid. Therefore, Applicant's claims 55-66, reciting the amino acid sequence set forth in SEQ ID NO:2, residues 17-677, cannot be anticipated by WO 00/20027. Accordingly, Applicant respectfully requests withdrawal of the rejection.

Applicant submits that this application is in condition for allowance. If the Examiner believes that issues remain to be addressed before a Notice of Allowance, Applicant respectfully requests that the Examiner contact the undersigned to discuss any outstanding issues.

Respectfully submitted,

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Dated: January 13, 2010 By: /Salvatore J. Arrigo/

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